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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/888,837 | 06/25/2001 | Anand V. Gumaste | MICRODOSE 00.01 | 9414 |
| 27667 | 7590 | 11/30/2004 | EXAMINER | |
| HAYES, SOLOWAY P.C. 130 W. CUSHING STREET TUCSON, AZ 85701 | | | PATEL, NIHIR B | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3743 | |

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|-----------------------------------|--|
| Office Action Summary | Application No. 09/888,837 | Applicant(s) GUMASTE, ANAND V. | |
| | Examiner Nihir Patel | Art Unit 3743 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on September 16th, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 8-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed on September 16th, 2004 have been fully considered but they are not persuasive. The applicant argues that Eisele's blister pack is not a flexible coiled tape but rather a plastic carrier disk that is sufficiently rigid. The examiner disagrees. Nowhere in Eisele's reference does it state that the blister pack is sufficiently rigid as stated in the applicant's arguments.

Applicant's arguments with respect to claims 1, 3, and 8 through 15 have been considered but are moot in view of the new ground(s) of rejection. Since the amended claims 1 and 13 contain new matter this rejection is made final.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 8, 13, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eisele et al. US Patent No. 5,921,237 in view of Eisele et al. US Patent No. 6,029,663.

Eisele discloses the applicant's invention as claimed with the exception of providing puncture holes formed in the top crown areas of the blister pack. Eisele discloses a dry powder inhaler delivery system that does provide puncture holes formed in the top crown areas of the blister pack. Therefore it would have been obvious to modify Eisele's invention by providing puncture holes formed in the top crown areas of the blister pack in order to make it easier to open.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eisele et al. U.S. Patent No. 5,921,237 in view of Pera U.S. Patent No. 5,944,012.

Eisele discloses the applicant's invention as claimed with the exception of stating that the material comprises a vitamin.

Pera discloses a method for dispensing antioxidant vitamin by inhalation background of the invention that does state that the material comprises a vitamin. Therefore it would be obvious to modify Eisele's invention by stating that the material comprises a vitamin so that one knows the limitations of the invention.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eisele et al. U.S. Patent No. 6,029,663 in view of Hendricks U.S. Patent No. 5,699,789.

Eisele discloses the applicant's invention as claimed with the exception of stating that the material comprises a hormone or a steroid.

Hendricks discloses a dry powder inhaler that does state that the material comprises a hormone or a steroid. Therefore it would be obvious to modify Eisele's invention by stating that the material comprises a hormone or a steroid so that one knows the limitations of the invention.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eisele et al. U.S. Patent No. 6,029,663 in view of Shyjan U.S. Patent No. 6,312,909.

Eisele discloses the applicant's invention as claimed with the exception of stating that the material comprises a bioactive material.

Shyjan discloses a compositions and methods for the diagnosis prevention and treatment of tumor progression that does state that the material comprises a bioactive material. Therefore it

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would be obvious to modify Eisele's invention by stating that the material comprises a bioactive material so that one knows the limitations of the invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Nihir Patel whose telephone number is (703) 306-3463. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful the examiner supervisor Henry Bennett can be reached at (703) 308-0101.

NP

November 16th, 2004

Henry Bennett
Supervisory Patent Examiner
Group 3700

